2014-1391

United States Court of Appeals for the Federal Circuit

PAR PHARMACEUTICAL, INC. and
ALKERMES PHARMA IRELAND LIMITED,

Plaintiffs – Appellants,

v.

TWI PHARMACEUTICALS, INC.,

Defendant – Appellee.

Appeal from the United States District Court for the District of Maryland in case no. 11-CV-02466-CCB, Judge Catherine C. Blake

NONCONFIDENTIAL DEFENDANT-APPELLEE TWI PHARMACEUTICALS, INC.'S MOTION TO DISSOLVE INJUNCTION PENDING APPEAL

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AUGUST 19, 2014

CERTIFICATE OF INTEREST

Pursuant to FED. CIR. R. 47.4, counsel for Appellee TWi Pharmaceuticals, Inc. certifies the following:

1. The full name of every party represented by me is:

TWi Pharmaceuticals, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

The party named in the caption is the real party in interest.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party represented by me are:

TWi Pharmaceuticals, Inc. is a publicly held stock company of Taiwan with no parent corporation. Although no longer a wholly owned subsidiary, TWi Pharmaceuticals Holdings, Inc. has a financial interest in TWi Pharmaceuticals, Inc. No publicly held corporation owns more than ten (10) percent of TWi Pharmaceuticals, Inc. or TWi Pharmaceuticals Holdings, Inc.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this court are:

Don J. Mizerk, Steven E. Feldman, Daniel R. Cherry, and John A. Sholar, Jr., all of Husch Blackwell LLP in Chicago, Illinois.

/s/ Don J. Mizerk
an Attorney for Defendant-Appellee
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August 19, 2014
Date

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CONFIDENTIAL MATERIAL OMITTED

Confidential infromation has been redacted from pages 3, 5, 6, 8,15 and 18 from this non-confidential version of the motion. The material on those pages was designated by Par Pharmaceutical, Inc. and/or TWi Pharmaceuticals, Inc. as confidential under the protective order dated April 19, 2012. They contain confidential Par Pharmaceutical, Inc. and/or TWi Pharmaceuticals, Inc. development and/or financial information.

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INTRODUCTION

Six months ago, in February 2014, the district court found that U.S. Patent 7,101,576 (the "'576 patent") is invalid, ending over two years of litigation initiated by Appellants Par Pharmaceutical, Inc. and Alkermes Pharma Ireland, Limited (collectively, "Par"). The district court's decision cleared the way for Appellee TWi Pharmaceuticals, Inc. ("TWi") to launch its generic version of Par's Megace ES as soon as FDA approves it. Par filed a notice of appeal and the appeal progressed at the normal pace. Par did nothing to extend an agreed preliminary injunction entered to allow the district court time to complete its opinion following trial, expedite the appeal, or even advise TWi that it would ever seek an injunction pending appeal.

Nevertheless, on July 18, 2014, Par filed a motion pursuant to Federal Rule of Civil Procedure 62(c) for an injunction pending appeal. Despite Par's delay, on August 12, 2014, the district court issued an injunction pending appeal based almost entirely on Par's statement that, without the Megace ES revenue, Par's Strativa department (which sells only Megace ES and one other product) would "likely be forced to close." (MA8.[1]) The district court conditioned the injunction

[1] TWi has filed an appendix with this Motion containing the district court's order and memorandum opinion, as well as the motion papers, declarations, and exhibits filed at the district court. In order to avoid any confusion with the Joint Appendix that will be filed in support of the merits briefing, TWi has used an "MA" prefix for the appendix related to this Motion.

on Par posting a $10 million bond and moving to expedite the appeal. (MA1.) TWi respectfully requests that this Court dissolve the lower court's injunction, as it was impermissibly granted.

Par's motion, filed nearly five months after the subject final judgment was entered, is without precedent. In nearly all instances, such motions are filed at the beginning of the appeal. When such issues are raised in this Court, the Court routinely sets an expedited briefing schedule to speed the consideration of the appeal and minimize the hardship on the parties. Because Par waited five months to seek this relief, the Court and TWi were deprived of the opportunity to meaningfully expedite the appeal and minimize the impact of a stay on TWi and the Court. This Court should dissolve the injunction and make it clear to Par that such motions should be filed, if at all, promptly following the judgment that is the subject of the appeal.

The Court should also use this opportunity to clarify the standard for obtaining an injunction or stay pending appeal under Federal Rule of Civil Procedure 62(c) and Federal Rule of Appellate Procedure 8. Here, the district court explicitly found that it was "not persuaded Par has demonstrated a 'strong' likelihood of success on appeal," but instead determined that it could still enter the injunction if it were convinced that a "substantial case" was raised in the appeal. (MA6.) The district court found that with a "substantial case" it could use a

"sliding scale" to impose an injunction even if likelihood of success on appeal was not shown. (MA3, 5.) This is not the law, however, and (as was the case here) would make obtaining an injunction pending appeal after the case was lost *easier* than before a decision on the merits at the preliminary injunction stage.

Finally, it was error for the district court to find that Par made a showing of irreparable harm. Here the district court relied on Par's assertion that it would "likely" close its Strativa *division* if it lost the Megace ES revenue. (MA8; MA253.) The facts are uncontested that Par has a billion dollars in annual revenue and that Megace ES provides only $20 million in annual operating profit. In other words, Par's *choice* of how to deal with this small loss of revenue and to "likely" quit subsidizing its Strativa division with other available corporate funds does not constitute irreparable harm unavoidably caused by TWi's market entry. (MA8.) Irreparable harm to support an injunction has to be unavoidable, not self-inflicted, as is admittedly the case here. Moreover, other than [redacted] If the loss of hundreds of millions in *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 134 S.Ct. 1621 (2014) did not constitute the required "irreparable harm," it is difficult to see how the loss of a tiny fraction of that revenue here could be.

This is not the way the process should operate. This Court should dissolve the injunction pending appeal due to Par's five-month delay, its failure to show the required "likelihood of success" and its failure to show any legally cognizable irreparable harm.

TWi has informed Par of this Motion and Par has indicated it will oppose it and will file a response.

BACKGROUND

This case stems from Appellee TWi's filing of an ANDA application with FDA seeking approval of its proposed megestrol acetate drug product for the treatment of wasting in AIDS patients. After receiving notice of TWi's filing, Par brought suit against TWi for infringement of one patent under the Hatch-Waxman Act. A five-day trial was held in October 2013.

After trial, but before the district court had issued its decision, Par was concerned about the imminent launch of TWi's product because of the expiry of the statutory 30-month stay afforded Par under the Hatch-Waxman Act. The parties agreed to a preliminary injunction (in the form of an agreed order with a $3 million bond) on January 20, 2014, which prevented TWi from launching its product until the district court entered final judgment. (MA516.)

On February 21, 2014, the district court issued its decision finding the asserted claims of the '576 patent obvious and invalid, and the district court

entered judgment in favor of TWi. After receiving the district court's decision, Par did nothing and allowed the injunction to lapse. Thus, TWi was free to launch its product as soon as it received final FDA approval.

Par recognized that TWi was free to launch its product following the district court's decision. On February 26, 2014, Par's General Counsel and Chief Administrative Officer, Mr. Haughey, sent a letter to TWi's President stating that

[redacted]

(MA314.) After sending the letter, Par did nothing. TWi remained free to launch its product as soon as it received final FDA approval.

Par recognized that TWi was free to launch its product following the district court's decision and Mr. Haughey's letter. In March 2014, Par told its investors in a 10-K SEC filing that "[t]he first generic filer has disclosed its intent to launch its ANDA product should it receive final FDA approval." (MA318.) Again, Par did nothing. TWi remained free to launch its product as soon as it received final FDA approval.

In May 2014, in its 10-Q filing, Par again stated that TWi had "disclosed its intent to launch its ANDA product. . . ." (MA325.) Par stated in the same document that:

> We expect the sales decline trend for Megace® ES experienced over the last few years as a result of an increasingly difficult

> reimbursement climate to continue or accelerate as the effects of the reduction of product detailing after January 31, 2013 are experienced and/*or when generic competition enters this market*.

(MA534.) Again, Par did nothing. TWi remained free to launch its product as soon as it received final FDA approval.

After acknowledging TWi's imminent launch for months, Par filed its principal brief on June 2, 2014, the due date automatically set by the applicable rules. TWi filed its principal brief on July 31, 2014. Par filed its reply on August 18, 2014, its due date. The appeal is fully briefed and awaiting oral argument and this Court's decision.

On July 18, 2014, five months after the district court entered judgment against Par and in favor of TWi and long after Par had filed its opening brief in this Court, Par filed a Fed. R. Civ. P. 62(c) motion at the district court for a temporary restraining order and an injunction pending appeal to block TWi from marketing its ANDA product upon FDA approval. In the declaration accompanying the motion, Par stated that [redacted] (MA253 (emphasis added).) [redacted] (MA480.) Par filed its next 10-Q on August 11, 2014, but surprisingly made no mention of this dire prediction. (MA530.) Par made no

statements in this 10-Q about the possible demise of Strativa, its branded division, as it told the district court. Par instead simply repeated its earlier statement that it expected Megace ES sales to continue to decline "when generic competition enters this market." (MA532.)

On August 12, 2014, after the matter was briefed below, the district court denied Par's motion for a temporary restraining order and granted their motion for an injunction pending appeal on the condition that Par both post a $10 million bond and sought expedited review of the pending appeal by this Court. Par filed a motion asking this Court to expedite its consideration of the fully briefed appeal last week. (D.E. 60.) No bond has yet been posted, but Par has indicated it plans to post the $10 million bond shortly.

ARGUMENT

Par's motion for an injunction pending appeal is unprecedented, as no appellant that TWi can locate has waited *nearly six months* after the entry of the subject final judgment to file such a motion. In addition, the district court mistakenly failed to acknowledge that *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008), which changed the preliminary injunction standard to eliminate any "sliding scale" and *required* the presence of *each* of the four factors, including a strong showing of likelihood of success. This necessarily also changed the standard for an injunction pending appeal, as the same standard applies in both

contexts. Finally, Par's argument that it [redacted] is legally insufficient to meet its required showing of irreparable harm.

I. A MOTION FOR A STAY OR INJUNCTION PENDING APPEAL SHOULD BE FILED WITHIN A REASONABLE TIME AFTER THE ENTRY OF THE SUBJECT FINAL JUDGMENT.

After nearly three years of litigation, a bench trial was held and the district court entered its finding on February 21, 2014 that TWi proved by clear and convincing evidence that the asserted claims of the '576 patent were invalid as obvious. The entry of the final judgment rendered the '576 patent invalid and permitted TWi to launch its generic Megace ES product upon FDA approval. Par sought injunctive relief in its complaint, but such relief was denied by the issuance of a final adverse judgment. This was the new "status quo" established by the final judgment—Par's patent was no longer a bar to the generic product. *See, e.g.*, *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 765 (D.C. Cir. 2010) (explaining that the Hatch-Waxman Act "struck a balance between expediting generic drug applications and protecting the interests of the original drug manufacturers").

Par filed a notice of appeal and the appeal has proceeded according to the Court's usual rules. However, when briefing was in its final stages, and nearly six months after the entry of the final judgment at issue, Par filed a motion pursuant to Federal Rule of Civil Procedure 62(c) for an injunction pending appeal.

An appellant should not be able to file a motion for stay pending appeal unless it does so early in the appeal. This is the normal course and the course clearly contemplated by the Federal Rules of Appellate Procedure. Federal Rule of Appellate Procedure 8 governs the motion and requires the motion to be made first in the district court pursuant to Federal Rule of Civil Procedure 62(c).

An injunction pending appeal is the exception and not the rule; it is an extraordinary remedy. *See, e.g., Teva Pharm.,* 134 S.Ct. at 1621. By filing such a motion at the beginning of the appeal, the appeals court can expedite the proceedings if an injunction pending appeal is entered *or* denied. This Court routinely provides such relief when requested at the beginning of the appeal. (*See, e.g.*, MA415 (Federal Circuit docket from *In re Cyclobenzaprine*; MA425 (Federal Circuit docket form *Eli Lilly & Co. v. Actavis Elizabeth LLC et al.*); MA437-38 (order denying injunction and expediting appeal in *Duramed v. Watson*); MA441-42 (order denying injunction and expediting appeal in *Hoffman La Roche v. Apotex et al.*).) By failing to move for an injunction pending appeal at the beginning of the appeal, Par denied the Court and TWi the opportunity to expedite the appeal.

This Court should find explicitly what most appellants seem to already understand: a motion to stay or for an injunction pending appeal should be filed, if at all, promptly at the beginning of the appeal.

II. THE DISTRICT COURT'S FINDING THAT PAR FAILED TO SHOW IT WAS LIKELY TO SUCCEED ON THE MERITS REQUIRED IT TO DENY THE INJUNCTION PENDING APPEAL.

In determining whether to grant an injunction pending appeal pursuant to Rule 62(c), four factors are considered: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987). The court below entered the injunction despite affirmatively holding that it was "**not persuaded Par has demonstrated a 'strong' likelihood of success** on appeal." (MA5 (emphasis added).) This was error. The district court's finding that Par had not demonstrated a strong likelihood of success on the merits *required it* to deny Par's motion for an injunction pending appeal.

The district court incorrectly asserted that even if a party failed to show a likelihood of success on the merits, an injunction pending appeal could be issued if the party "can nonetheless demonstrate a substantial case on the merits." (MA5.) The district court noted that it could not find "clear authority" whether it should apply Federal Circuit or Fourth Circuit law, but that both circuits applied the same test. (MA3 at n.1.) This was error, as the Federal Circuit has clearly stated that the law of the regional circuit, not the Federal Circuit, applies to procedural questions

such as stays and injunctions. *See Aevoe Corp. v. AE Tech Co., Ltd.*, 727 F.3d 1375, 1381 (Fed. Cir. 2013) ("The grant, denial, or modification of a preliminary injunction . . . is not unique to patent law, so this court applies the law of the regional circuit when reviewing and interpreting such a decision."); *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, Nos. 2011-1538, -1567, 2012-1129, -1201, 2012 WL 10716768, at *1 (Fed. Cir. Apr. 2, 2012) ("This court applies the procedural law of the relevant regional circuit when reviewing a district court's decision to grant or deny a motion for a stay under Rule 62(d) of the Federal Rules of Civil Procedure.").

The district court compared the Rule 62 analysis in *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 513 (Fed. Cir. 1990) to *Long v. Robinson*, 432 F.2d 977, 979 (4th Cir. 1970). (MA3 at n.1.) The district court, however, erred because this aspect of both cases was overruled when the U.S. Supreme Court issued its opinion in *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 23 (2008), where in the context of a preliminary injunction, the Court rejected the "sliding scale" test and required a party seeking an injunction to show both "likelihood of success" and "irreparable harm." *Real Truth About Obama, Inc. v. Federal Election Com'n*, 575 F.3d 342, 346 (4th Cir. 2009), *vacated on other grounds by* 130 S.Ct. 2371 (2010); *see also Conestoga Wood Specialties Corp. v. Sec'y of the United States Dep't of Health & Human Servs.*, No. 13-1144,

2013 WL 1277419, at *1 (3d Cir. Feb. 8, 2013) ("[a] plaintiff's failure to establish any element in its favor renders a stay pending appeal inappropriate."); *U.S. v. Cooper Health Sys*, 958 F. Supp. 2d 564, 569 (D.N.J. 2013) (same); *Combs v. FV-1, Inc*., No. MJG-13-3734, 2013 WL 6662729, at *4 (D. Md. Dec. 16, 2013) ("[Movant] must satisfy each element for relief…."); *In re Harenberg*, 491 B.R. 706, 716 (D. Md. 2013) ("The burden rests on the moving party to establish each element….").

Par attempted to argue that the *Winter* rule applied only to preliminary injunctions under Federal Rule of Civil Procedure 65 and not to requests for a stay pending appeal under Federal Rule of Civil Procedure 62(c) or Federal Rule of Appellate Procedure 8(a), stating:

> A preliminary injunction under Rule 65 requires an independent showing on each prong. *See Winter v. NRDC*, 555 U.S. 7 (2008); *Real Truth About Obama, Inc. v. Fed. Election Comm'n*, 575 F.3d 342 at 345-47 (4th Cir. 2009). But stays pending appeal are governed by Rule 62(c), and the Fourth Circuit has not decided whether the *Winter* standard should be applied in this context.

(MA28 at n.1.) But Par[2] failed to note that the Fourth Circuit and other courts have determined that the standards must be at least the same and, if anything, the standard for a stay pending appeal would be higher than the preliminary injunction

[2] While citing *Real Truth,* Par failed to articulate to the trial court that the Fourth Circuit expressly jettisoned the old "sliding scale" approach in that case and found that *Winter* required an independent analysis of each factor under Fed. R. Civ. P. 65. *Real Truth*, 575 F.3d at 346. The Fourth Circuit's analysis in *Real Truth* applies with equal force to injunctions under Fed. R. Civ. P. 62.

standard. *See Conestoga Wood*, 2013 WL 1277419, at *1 ("[T]he standard for obtaining a stay pending appeal is essentially the same as that for obtaining a preliminary injunction."); *Blackwelder Furniture Co. of Statesville, Inc. v. Seilig Mfg. Co., Inc.*, 550 F.2d 189, 193 (4th Cir. 1977) (The four-part test established in *Blackwelder* to grant preliminary injunctions evolved from the same "fourfold equitable rule of thumb" as the one laid out in *Long* for granting a stay pending appeal.); *Coler v. Draper*, No. WDQ-12-2020, 2012 WL 5267436, at *3 (D. Md. Oct. 23, 2012) ("In the Fourth Circuit, the standard for a stay pending appeal of a bankruptcy court's decision is that for a preliminary injunction."); *Davis v. Taylor*, No. 2:12-3208-RMG-BM, 2012 WL 6055452, at *3 (D.S.C. Nov. 16, 2012) (applying the four-factor *Real Truth* test for a motion to stay pending an appeal); *Ohio Valley Envtl. Coalition, Inc. v. U.S. Army Corps of Eng'rs*, 890 F. Supp. 2d 688, 693 (S.D. W. Va. 2012) ("[I]t would be problematic and unfair to allow Plaintiffs to further delay based on a showing much lower than that required for them to have received a preliminary injunction in the first place.").

Hilton requires a "strong showing" that the moving party is "likely to succeed on the merits" in order to grant an injunction pending appeal. *Hilton*, 481 U.S. at 776. The district court found that it was "**not persuaded Par has demonstrated a 'strong' likelihood of success** on appeal." (MA5 (emphasis added).) For the reasons stated above, after *Winter* and *Real Truth* there is no

sliding scale approach that allows for the issuance of an injunction when this factor is not met. Because this element was not met, the district court should not have granted an injunction. TWi requests that the Court correct this error and lift the injunction issued by the lower court.

III. PAR'S CHOICE TO *POSSIBLY* "RESTRUCTURE" IF IT LOSES MEGACE ES REVENUE IS NOT IRREPARABLE HARM.

In addition to the failure to show likelihood of success on the merits, the failure of a party seeking an injunction pending appeal to show irreparable harm also requires the denial of the motion. *Winter*, 555 U.S. at 22. The district court found that irreparable harm existed because, "Par has also demonstrated that the lost revenue will likely force its entire branded division, Strativa, to shut down." (MA7.) First, Par's asserted threat that it *will possibly* shut down its Strativa department if it loses the $20 million in Megace ES operating profit is the kind of speculative harm that cannot support a finding of irreparable harm as a matter of law. It is a choice, not a necessary consequence of TWi's generic launch. Second, Par's purported harms are compensable by money damages. Because Par cannot meet this prong of the test as a matter of law, no injunction should have issued.

A. Plaintiffs' Choice To Shutter A Division In The Face Of Lost Revenue Is Not Irreparable Harm.

The district court erred when it found that the launch of TWi's ANDA product was likely to result in the shuttering of Par's branded division, Strativa.

Confidential Material Redacted

The district court's finding was based on two declarations filed by John Ameres, an employee of Par. In the first declaration, Ameres stated that [redacted] (MA253 at ¶17).) In the second declaration, Ameres reiterates the same argument, stating that it would be [redacted] (MA507 at ¶9).)

This type of speculation cannot support an injunction as a matter of law. Par does not say anywhere in its submissions that a single job will be lost. Nor does Par state that it will stop selling Megace ES or its one other branded drug product. Instead, Par offers a triple-qualified insinuation [redacted][3] [redacted] (MA507.) Par never states what this means. Interestingly, days after submitting its declarations, Par issued another 10-Q statement that made no mention of this potential dire consequence. (MA530 ("Recent Developments" section).) Par simply stated that it expected Megace ES sales to continue to decline "when generic competition enters this market." (MA532.) The courts are rightfully suspicious of statements made in connection

[3] Par already fired 70 sales representatives in preparation for its guilty plea for the criminal misbranding of Megace ES. (MA325.)

with a motion for an injunction that are much more dire than those made to the public markets. *See, e.g., In re Fenofibrate Patent Litigation*, 972 F. Supp. 2d 655, 657 (S.D.N.Y. 2013) ("[T]he Court has little difficulty finding that Proctor's declaration materially overstated the risk of job losses that would result from generic competition to Antara.").

Par also supplied the district court with expert declarations from an economist. Based on those declarations, the district court found that "Par [estimates that it] will lose $20 million in annual operating profits should a generic enter the market." (MA13.) Last quarter Par reported revenue of $278.8 million. (MA526.) In that same quarter, Strativa reports a loss of nearly $9 million. (*Id.*)

Put simply, Strativa, even if it were a separate business, is already operating at a loss and Par has made a business decision to keep it going. (MA526.) If Par experiences additional compensable financial losses (which it as estimated at $20 million) it may continue to make business decisions regarding which aspects of its business to keep and which to discontinue. Those internal decisions regarding what to do in the face of a measurable pecuniary loss do not change a compensable harm into an irreparable one.

B. Par's Alleged Damage Is Compensable; Therefore No Injunction Should Have Been Granted.

Economic damages do not constitute irreparable harm for the purposes of an injunction. And, based on the facts asserted in their motion, Par cannot make the

"clear showing" that their alleged harms will be irreparable. *Winter*, 555 U.S. at 22. Irreparable harm is harm that is non-economic and is "of a peculiar nature, so that compensation in money cannot atone for it." *Harsco Corp. v. Novetas Solutions, LLC*, No. 13-cv-2726, 2014 WL 2041818, at *4 (M.D. Pa. May 16, 2014); *see also Virginia Carolina Tools, Inc. v. Int'l Tool Supply, Inc.*, 984 F.2d 113, 120 (4th Cir. 1993) (upholding a district court finding that "expenses incurred in relocation, injury to reputation, loss of profits" and other "highly speculative and largely economic injuries" did not constitute irreparable harm); *see also Taylor v. Resolution Trust Corp.*, 56 F.3d 1497, 1507 (D.C. Cir. 1995) ("[I]n the absence of special circumstances, . . . recoverable economic losses are not considered irreparable.").

Par's potential harms are hardly "peculiar." Par offers only boilerplate arguments universally invoked by pharmaceutical companies seeking to maintain monopoly pricing at the expense of legitimate generic competition. Such arguments have been rejected by district and appellate courts, and most recently by the Chief Justice of the United States Supreme Court. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 134 S.Ct. 1621 (2014) (denying a motion for a stay of a mandate stemming from the Federal Circuit and noting that "should Teva prevail in this Court and its patent be held valid, Teva will be able to recover damages from respondents for past patent infringement. Given the availability of that remedy, the

extraordinary relief that Teva seeks is unwarranted.") (citation omitted). If the boilerplate harms that Par articulates were to constitute irreparable harm, the conclusion would translate to a *per se* rule that generic entry causes irreparable harm to companies selling branded drugs. *See, e.g., Altana Pharma AG v. Teva Pharm. USA, Inc.*, 532 F. Supp. 2d 666, 683 (D.N.J. 2007). No such rule exists.

Further underscoring the lack of irreparable harm, Par's expert has provided an estimate of what Plaintiffs' money damages would be. Dr. Vandeale's declaration states that [redacted] (MA261 (emphasis added).) This is compensable, and therefore Par should not have been granted an injunction pending appeal. Moreover, these types of losses in this context are seldom seen as sufficient to support the issuance of any injunction. *Mylan Labs., Inc. v. Leavitt*, 495 F. Supp. 2d. 43, 48-49 (D.D.C. 2007); *Lightfoot v. District of Columbia*, No. 01–1484(CKK), 2006 WL 175222, at *8 (D.D.C. Jan. 24, 2006) (holding that losses must threaten the survival of a business); *Varicon Int'l v. Office of Personnel Mgmt.*, 934 F. Supp. 440, 447-48 (D.D.C. 1996) (finding no irreparable harm due to a lost contract where the movant's revenue would decline by ten percent); *Bristol–Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 220-21, n.12 (D.D.C. 1996) (finding no irreparable harm where the movant would lose eighty million dollars—less than one percent of its total sales); *TGS Tech., Inc. v.*

U.S., Dept. of Air Force, No. 92–0062, 1992 WL 19058, at *3-4 (D.D.C. Jan. 14, 1992) (finding no irreparable harm where a lost contract constituted twenty percent of the movant's business).

Thus, Par's potential loss of $20 million in operating profit, when considered in the context of its entire business, cannot constitute irreparable harm as a matter of law.

CONCLUSION

For the foregoing reasons, the district court's improvidently granted injunction pending appeal should be lifted and TWi should be free to launch its generic megestrol acetate product as soon as it receives final FDA approval.

Respectfully Submitted,

Date: August 19, 2014

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United States Court of Appeals
for the Federal Circuit

Par Pharmaceutical, Inc. v. TWi Pharmaceuticals, Inc., 2014-1391

CERTIFICATE OF SERVICE

I, Elissa Matias, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by HUSCH BLACKWELL LLP, Attorneys for Appellee to print this document. I am an employee of Counsel Press.

On **August 19, 2014** counsel has authorized me to electronically file the foregoing **Motion to Dissolve Injunction Pending Appeal (confidential and non-confidential versions)** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to all counsel registered as CM/ECF users, including any of the following:

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Confidential copies will be emailed to the above counsel and paper confidential copies will also be mailed to the above principal counsel on this date.

August 19, 2014

/s/ Elissa Matias
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